COMMERCIAL INTERNAL RESEARCH SOFTWARE LICENSE AGREEMENT

This **Agreement** is based on the model Commercial Internal Research Software License Agreement for commercial entities adopted by the U.S. Public Health Service ("**PHS**") Technology Transfer Policy Board for use by components of the National Institutes of Health ("**NIH**"), the Centers for Disease Control and Prevention ("**CDC**"), and the Food and Drug Administration ("**FDA**"), which are agencies of the **PHS** within the Department of Health and Human Services ("**HHS**").

This Cover Page identifies the Parties to this Agreement:between

The U.S. Department of Health and Human Services, as represented by

[Insert the full name of the IC]

an Institute or Center (hereinafter referred to as the "IC") of the

[INSERT as appropriate: NIH, CDC, or FDA]

and

[Insert Company's official name],

hereinafter referred to as the "Licensee",

having offices at [Insert Company's address],

created and operating under the laws of [Insert State of Incorporation].

Tax ID No.:

The IC and the Licensee agree as follows:

- 1. In the course of official duties, the **IC** employees created certain proprietary software in the form or executable code, source code, or object code and associated materials, as described in Appendix A, (hereinafter "**Software**").
- 2. The United States Government, owns the **Software**. The Secretary for Health of **HHS** has delegated to the **IC** the authority to enter into this **Agreement** for the licensing of inventions owned by the United States Government.
- 3. The **IC** hereby grants and the **Licensee** accepts, subject to the terms and conditions of this **Agreement**, a term limited, nontransferable, non-exclusive internal research license to use the **Software**, as hereinafter defined with no provision for support, in order to conduct research and develop processes, methods, or marketable products for public use and benefit.
- 4. The **IC** reserves the right to distribute **Software** to others and to use it for any U.S. Government purpose. The **IC** shall not be limited in future claims, publications, or distributions of **Software** or modifications or versions thereof, or related information. No copyright to **Software** is claimed in the United States under <u>Title 17, U.S. Code</u>.
- 5. **Licensee** agrees that the **IC** retains title to the **Software** and **Licensee** agrees not to interfere and to prevent others from interfering with the **IC's** right in title. It is understood that nothing herein shall be deemed to constitute, by implication or otherwise, the grant of any license or other rights under any patent, patent application or other intellectual property right or interest.
- 6. The **Licensee** agrees to use the **Software** solely for internal research purposes, only on one single computer by one single user at any one time per each license acquired. The **Licensee** shall not make any copies, except for its internal use.
- 7. The **Licensee** agrees to retain control over **Software** and to employ all reasonable efforts to safeguard the **IC's** rights in **Software**. The **Licensee** agrees to ensure that no third party shall have access thereto and that no unauthorized copy, publication, disclosure, transfer or distribution, in whole or in part, in any form shall be made of **Software**, neither the source code, nor the executable code, nor associated run-time applications, whether standalone or embedded, for use by any third party without the express prior written approval of the **IC**. To the extent permitted by law, the **Licensee** agrees to take appropriate action with its employees to satisfy its obligation under this **Agreement** with respect to maintaining the above degree of protection for **Software**.
- 8. The **Licensee** shall not modify or extend **Software** without written permission from the **IC**. The **Licensee** is encouraged to send to the **IC** general reports regarding the application of the **Software** and the effectiveness and problems encountered in using **Software**, without disclosing the **Licensee's** confidential information. Information from general reports may be used by the **IC** to enhance the capabilities of **Software**. The **Licensee's** interest in modifying or extending **Software** shall be addressed to the Lead Inventor named in Appendix A.
- 9. **Software**, or any modified or embedded version thereof, shall not be published by the **Licensee** for profit to, nor in any manner offered for sale to, the U.S. government or any other entity or firm. **Software** may be used in a contract with the U.S. government, but no charge may be made for its use.
- 10. The **Licensee** has no right to grant sublicenses to the **Software** licensed hereunder.
- 11. The **Licensee** may publish or otherwise publicly disclose the results of using the **Software**. The **Licensee** agrees to acknowledge the **IC's** contribution of the **Software** in all written publications containing any data

- or information regarding or resulting from use of the **Software.** The **Licensee** shall cite the origin of the **Software** as stated in the Acknowledgments section in Appendix A.
- 12. The **Licensee** agrees in its use of the **Software** to comply with all the applicable **NIH** regulations and guidelines. The **Licensee** agrees that **Software** MAY NOT BE USED FOR TREATING OR DIAGNOSING HUMAN SUBJECTS. The **Licensee** agrees not to use the **Software** for research involving human subjects or clinical trials in the United States without complying with 21 C.F.R. Part 50 and 45 C.F.R. Part 46. The **Licensee** agrees not to use the **Software** for research involving human subjects or clinical trials outside of the United States without notifying the **IC**, in writing, of such research or trials and complying with the applicable regulations of the appropriate national control authorities. Written notification to the **IC** of research involving human subjects or clinical trials outside of the United States shall be given no later than sixty (60) days prior to commencement of such research or trials.
- 13. **Licensee** agrees in its use of the **Software** to comply with all applicable Federal laws, statutes, regulations, and guidelines, including the Export Administration Act of 1979 and Arms Export Control Act, controlling the export of technical data, computer software, laboratory prototypes, and other commodities. The transfer of such items may require a license from the cognizant agency of the U.S. Government or written assurances by the **Licensee** that it shall not export such items to certain foreign countries without prior approval of such agency. The **IC** neither represents that a license is or is not required or that, if required, it shall be issued.
- 14. The **Licensee** acknowledges that the **Software** is a research tool still in the development stage and that it is being supplied AS IS, WITHOUT ANY ACCOMPANYING SERVICES OR IMPROVEMENTS from the **IC**. All risk as to quality and performance of the **Software** is with the **Licensee**. The **IC** shall be neither liable nor responsible for any maintenance or updating of the **Software**, nor for correction of any errors in the **Software**. In no event will the **IC** be liable to the **Licensee** for damages arising out of the use or inability to use the **Software**, including but not limited to loss of data or data being rendered inaccurate or losses sustained by the **Licensee** or third parties.
- 15. THE IC MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, OR STATUTORY, INCLUDING, BUT NOT LIMITED TO, ANY WARRANTY THAT SOFTWARE WILL CONFORM TO SPECIFICATIONS, ANY IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR THAT THE USE OF THE SOFTWARE WILL NOT INFRINGE ANY PATENT, COPYRIGHT, OR TRADEMARK, OR ANY WARRANTY THAT THE DOCUMENTATION WILL CONFORM TO THE PROGRAM OR THAT SOFTWARE WILL BE ERROR FREE OR OTHER RIGHTS OR ANY OTHER EXPRESS OR IMPLIED WARRANTIES. In no event shall the IC be liable for any damages, including, but not limited to direct, indirect, special or consequential damages, arising out of, resulting from, or in any way connected with the performance or breach of this license, whether or not based upon warranty, contract, tort or otherwise, whether or not injury was sustained by persons or property or otherwise, and whether or not loss was sustained from, or arose out of the any use, results or disposition of, the Software or services provided hereunder.
- 16. THE **Licensee** agrees to waive any and all claims against, and to indemnify and hold harmless the U.S. Government, its employees, students, fellows, agents, consultants, contractors and subcontractors for any damage that the **Licensee** may incur from the **Licensee**'s prior or future use of the **Software**, including any damages resulting from products based on results from the use thereof. The **Licensee** agrees to obtain this identical waiver of claims, indemnification and hold harmless agreement with any entities that are provided with technical data derived from the use of the **Software**.
- 17. The **Licensee** agrees not to claim, infer, or imply endorsement by the U.S. Government, **HHS** or **IC** of the research results obtained using the **Software**, or any resulting product(s). The **Licensee** agrees, to the extent permitted by law, not to identify the U.S. Government, **IC**, **HHS** or **NIH** in any promotional advertising or other promotional materials to be disseminated to the public or any portion thereof or to use the name of any nonconsenting U.S. Government employee, without **IC**'s prior written consent.

- 18. The **Licensee** agrees to pay to the **IC** a noncreditable, nonrefundable license issue royalty within thirty (30) days of being invoiced for the same, as set forth in Appendix A. The **IC** will provide the **Software** to the **Licensee** in a computer readable media format or deliver instructions and a password to allow the **Licensee** to download the **Software**, upon receiving verification that such payment was made and no later than thirty (30) days after receiving such verification.
- 19. All payments under this **Agreement** shall be paid in U.S. dollars. For conversion of foreign currency to U.S. dollars, the conversion rate shall be the New York foreign exchange rate quoted in *The Wall Street Journal* on the day that the payment is due. All checks and bank drafts shall be drawn on United States banks and shall be payable, as appropriate, to "NIH/Patent Licensing". All such payments shall be made or be sent to the address indicated in Appendix B. Any loss of exchange, value, taxes, or other expenses incurred in the transfer or conversion to U.S. dollars shall be paid entirely by the **Licensee**.
- 20. The effective date of this **Agreement** shall be the date on which the last party signs this **Agreement** unless the provision of Paragraph 25 is not fulfilled.
- 21. In the event that the **Licensee** is in default in the performance of any material obligations under this **Agreement**, and if the default has not been remedied within ninety (90) days after the date of notice in writing of such default, the **IC** may terminate this **Agreement** by written notice.
- 22. The **IC** reserves the right according to <u>35 U.S.C. §209(d)(3)</u> to terminate or modify this **Agreement** if its is determined that such action is necessary to meet requirements for public use specified by Federal regulations issued after the date of the license and such requirements are not reasonably satisfied by the **Licensee**.
- 23. The provisions of this **Agreement** are severable, and in the event that any provision of this **Agreement** shall be determined to be invalid or unenforceable under any controlling body of law, such determination shall not in any way affect the validity or enforceability of the remaining provisions of this **Agreement**.
- 24. The construction, validity, performance, and effect of this **Agreement** shall be governed by Federal law as applied by the Federal Courts in the District of Columbia.
- 25. The terms and conditions of this **Agreement** shall, at the **IC's** sole option, be considered by the **IC** to be withdrawn from the **Licensee's** consideration and the terms and conditions of this **Agreement**, and the **Agreement** itself to be null and void, unless this **Agreement** is executed by the **Licensee** and a fully executed original is received by the **IC** within sixty (60) days from the date of the **IC's** signature found at the Signature Page.

COMMERCIAL INTERNAL RESEARCH SOFTWARE LICENSE AGREEMENT

SIGNATURE PAGE

For IC :	
Name Title Office National Institutes of Health	Date
For the Licensee (Upon, information and belief, the undersigned express any statements of the Licensee made or referred to in this document are	
Signature of Authorized Official	Date
Title	-
Address for Notices	

Any false or misleading statements made, presented, or submitted to the United States Government or any agency thereof, including any relevant omissions, under this **Agreement** and during the course of negotiation of this **Agreement** are subject to all applicable civil and criminal statutes including Federal statutes 31 U.S.C. §§3801-3812 (civil liability) and 18 U.S.C. §1001 (criminal liability including fine(s) and/or imprisonment).

APPENDIX A

Software Description:	

Acknowledgments:	

Inventor:	
Royalties:	
A noncreditable, nonrefundable license one-time royalty in the amount of:	
1-4 user seats, at USD\$XXX per license. Number of Seats:	Total : USD\$
5-11 user seats, at USD\$XXX per license. Number of Seats:	Total : USD\$
12+ user seats at USD\$XXX per license. Number of Seats:	Total · USD\$

Appendix B – Royalty Payment Options

New Payment Options Effective March 2018

The License Number MUST appear on payments, reports and correspondence.

Credit and Debit Card Payments: Credit and debit card payments can be submitted for amounts up to \$24,999. Submit your payment through the U.S. Treasury web site located at: https://www.pay.gov/public/form/start/28680443.

Automated Clearing House (ACH) for payments through U.S. banks only

The IC encourages its licensees to submit electronic funds transfer payments through the Automated Clearing House (ACH). Submit your ACH payment through the U.S. Treasury web site located at: https://www.pay.gov/public/form/start/28680443. Please note that the IC "only" accepts ACH payments through this U.S. Treasury web site.

<u>Electronic Funds Wire Transfers:</u> The following account information is provided for wire payments. In order to process payment via Electronic Funds Wire Transfer sender MUST supply the following information within the transmission:

Drawn on a **U.S. bank account** via FEDWIRE:

Please provide the following instructions to your Financial Institution for the remittance of Fedwire payments to the **NIH ROYALTY FUND**.

Fedwire Field Tag	Fedwire Field Name	Required Information	
Tield Tag			
{1510}	Type/Subtype	1000	
{2000}	Amount	(enter payment amount)	
{3400}	Receiver ABA routing number*	021030004	
{3400}	Receiver ABA short name	TREAS NYC	
{3600}	Business Function Code	CTR (or CTP)	
{4200}	Beneficiary Identifier (account number)	(enter 12 digit gateway account #) 875080031006	
{4200}	Beneficiary Name	(enter agency name associated with the Beneficiary Identifier) DHHS / NIH (75080031)	
{5000}	Originator	(enter the name of the originator of the payment) COMPANY NAME	
{6000}	Originator to Beneficiary Information – Line 1	(enter information to identify the purpose of the payment) ROYALTY	
{6000}	Originator to Beneficiary Information – Line 2	(enter information to identify the purpose of the payment) LICENSE NUMBER	
{6000}	Originator to Beneficiary Information – Line 3	(enter information to identify the purpose of the payment) INVOICE NUMBER	
{6000}	Originator to Beneficiary Information – Line 4	(enter information to identify the purpose of the payment)	
Notes: *The financial institution address for Treasury's routing number is 33 Liberty Street, New York, NY 10045.			

Agency Contacts: Office of Technology Transfer (OTT) (301) 496-7057 OTT-Royalties@mail.nih.gov

Drawn on a **foreign bank account** via FEDWIRE:

The following instructions pertain to the Fedwire Network. Deposits made in <u>US Dollars (USD)</u>.

Should your remitter utilize a correspondent US domestic bank in transferring electronic funds, the following Fedwire instructions are applicable.

Fedwire Field Tag	Fedwire Field Name	Required Information
{1510}	Type/Subtype	1000
{2000}	Amount	(enter payment amount)
{3100}	Sender Bank ABA routing number	(enter the US correspondent bank's ABA
		routing number)
{3400}	Receiver ABA routing number*	021030004
{3400}	Receiver ABA short name	TREAS NYC
{3600}	Business Function Code	CTR (or CTP)
{4200}	Beneficiary Identifier (account number)**	(enter 12 digit gateway account #)
		875080031006
{4200}	Beneficiary Name	(enter agency name associated with the
		Beneficiary Identifier)
		DHHS / NIH (75080031)
{5000}	Originator	(enter the name of the originator of the
		payment)
		COMPANY'S NAME
{6000}	Originator to Beneficiary Information – Line 1	(enter information to identify the purpose of the
		payment)
		ROYALTY
{6000}	Originator to Beneficiary Information – Line 2	(enter information to identify the purpose of the
		payment)
		LICENSE NUMBER
{6000}	Originator to Beneficiary Information – Line 3	(enter information to identify the purpose of the
		payment)
		INVOICE NUMBER
{6000}	Originator to Beneficiary Information – Line 4	(enter information to identify the purpose of the
		payment)

Notes:

Agency Contacts:

Office of Technology Transfer (OTT) (301) 496-7057 OTT-Royalties@mail.nih.gov

^{*}The financial institution address for Treasury's routing number is 33 Liberty Street, New York, NY 10045.

^{**}Anything other than the 12 digit gateway account # will cause the Fedwire to be returned – **SWIFT CODE: FRNYUS33**

Checks

All checks should be made payable to "NIH Patent Licensing"

Checks drawn on a <u>U.S. bank account</u> and sent by US Postal Service should be sent directly to the following address:

National Institutes of Health P.O. Box 979071 St. Louis, MO 63197-9000

Checks drawn on a U.S. bank account and sent by **overnight or courier** should be sent to the following address:

US Bank Government Lockbox SL-MO-C2GL 1005 Convention Plaza St. Louis, MO 63101 Phone: 314-418-4087

Checks drawn on a **foreign bank account** should be sent directly to the following address:

National Institutes of Health Office of Technology Transfer License Compliance and Administration Royalty Administration 6011 Executive Boulevard Suite 325, MSC 7660 Rockville, Maryland 20852